## APPENDIX 1

(Second Farace Declaration)

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Wolfgang Woloszczuk et al.

Serial No.: 10/596,968

Filed: June 30, 2006

For: IDENTIFICATION OF FELINE OR

CANINE proBNP

Confirmation No.: 3302

Group Art Unit: 1641

Examiner: FOSTER, Christine E.

Atty. Dkt. No.: SONN:093US

## DECLARATION OF GIOSI FARACE UNDER 37 C.F.R. §1.132

I, Giosi Farace, the undersigned, declare that:

- 1. I am a Research Scientist II at Idexx Laboratories, Inc. I have extensive research experience in protein detection and antibody-based diagnostic assays. A copy of my curriculum vitae, listing my publications in this regard, is attached as Exhibit A.
- I am providing this declaration to describe certain studies performed at Idexx Laboratories regarding the detection of proBNP in canine plasma. These studies were performed to assess the ability of antibodies raised against the polypeptide HPLGGRSPASEAEASGLQELLG or KDAVSELQAEQLALEPL to detect proBNP in a canine plasma sample. These studies, which are described in more detail below, confirm that these antibodies successfully recognize and bind to canine proBNP that is present in a feline plasma sample.
- 3. Canine plasma samples were contacted with a "capture" antibody in order to enrich for proBNP in the sample. The "capture" antibody used was a sheep polyclonal antibody directed against amino acids KDAVSELQAEQLALEPL of canine proBNP.

- acids 4. Next, sheep polyclonal antibody directed against amino HPLGGRSPASEAEASGLQELLG was used to detect the proBNP in the enriched samples. Exhibit B describes the procedure used to detect proBNP in the canine plasma samples. The detection antibody was added at step 4 of the procedure. Exhibit C provides the data obtained, which show that the antibodies directed against HPLGGRSPASEAEASGLQELLG or KDAVSELQAEQLALEPL successfully recognized and bound to canine plasma proBNP.
- 5. I previously provided a declaration ("the First Farace Declaration") describing certain studies performed at Idexx Laboratories regarding the species specificity of antibodies against NTproBNP fragments. A copy of this declaration is attached as Exhibit D. This paragraph provides additional information about the amino acid sequences referenced in the First Farace Declaration. The peptide referred to as "amino acids 1-20" in feline proBNP in the First Farace Declaration has the amino acid sequence: HPLGGPGPASEASAIQELLD. The peptide referred to as "amino acids 60-80" in feline proBNP in the First Farace Declaration has the amino acid sequence: VLAPHDNVLRALRRLGSSKM. The peptide referred to as "amino acids 1-22" in canine proBNP in the First Farace Declaration has the amino acid sequence: HPLGGRSPASEAEASGLQELLG. The peptide referred to as "amino acids 25-41" in canine proBNP in the First Farace Declaration has the amino acid sequence: KDAVSELQAEQLALEPL.

6. I declare that all statements made herein of my own knowledge are true, and that all statements of my own belief are believed to be true, and further that these statements were made with the knowledge that willful false statements are punishable by fine or imprisonment, or both, under § 1001 of title 18 of the United States Code.

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## **EXHIBIT A**